

## **Breakout Discussion and Decisions: Analytical Chemistry**

### Linearity

Linearity is method specific. Therefore, the lab must provide documented evidence of their calibration criteria.

### Method Validation

For initial method validation, at least 7 tests must be done, keeping in mind that industry prescriptive methods may set other specific criteria.

Acceptance criteria for spike recovery is method specific. Therefore, assessors need to rely on scientific judgement and reference method performance.

### ICP – 3 vs 1 Standards

One method validation is completed, one blank and one standard must be done with each run to verify calibration. Major instrument changes trigger revalidation of the operating range.

### BTEX/PCB

Method validation is required to characterize linearity and operating parameters. One control standard must be done each run to verify calibration.

There is no set policy or guidance on frequency of multipoint calibration.

### Duplicates

When samples routinely have concentrations <MDL, duplicates of the control standards to obtain duplicate statistics can be performed.

### CCME – Petroleum Hydrocarbons

Appendices where the method reference is “CCME” or “based on CCME...” must be assessed using the test specific checklist to ensure that the laboratory is actually using the CCME method.

**Action Item:** It was believed that guidelines values were required to be updated, but after investigating this issue, it turns out that Rev. 1.1 of the CCME checklist is accurate.

## Flashpoint

Several points in the appendix checklist are “not applicable”. A key element to assess is that an appropriate ASTM thermometer is used.

**Action Item:** Will post any further information that is necessary on the assessor-protected area of the web site.

## Expiry of Standards

Option 1 – Discard expired standards.

Option 2 – Re-validate and continue using for instrument calibration, recognizing that some high level standards may be fine past the expiry date. However, there is a liability associated with this approach, and there is also a question of assessing the in-house protocol used to validate standards.

Decision: CAEAL is taking this issue to TG Labs for a comprehensive decision. In the interim the following is the policy that will be followed by CAEAL labs and assessors.

1. Laboratories may use expired standards, if and only if, the following conditions are met, and can be demonstrated during an assessment:
  - a. The laboratory must document and maintain sets of data that demonstrate that the expired standard continues to be fit for purpose.
  - b. Such data is to provide consistent results, using statistically valid data, to demonstrate that the standard continues to perform with an uncertainty at least as acceptable as the uncertainty noted on the documentation accompanying the standard. When laboratory data demonstrates that this condition is no longer met, the standard is to be considered no longer fit for purpose.
  - c. If there is no uncertainty associated with the standard upon purchase, the laboratory is to determine the performance criteria of the standard and document acceptability criteria for use beyond the expiry date. Laboratories that fail to develop acceptance criteria prior to the expiry of a standard, in this case, cannot continue to use the standard beyond the expiry date.